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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/665,314

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James J. Cali

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

10/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/665,314	Applicant(s) CALI ET AL.	
	Examiner Susannah Chung	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-167 is/are pending in the application.
- 4a) Of the above claim(s) 1-131 and 143-167 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 132-142 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/7/04, 11/1/04, 12/17/04, 1/14/05, 6/15/07.

DETAILED ACTION

Claims 1-167 are pending in the instant application.

Priority

This application claims benefit of 60/412,254, filed 9/20/02, and claims benefit of 60/483,309, filed 6/27/03.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 6/7/04, 11/1/04, 12/17/04, 1/14/05, and 6/15/07 have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Election/Restrictions

Applicant's election with traverse of Group X, claims 132-142, in the reply filed on 7/27/2006 is acknowledged. Specially, the election of species of luciferin 6' benzyl ether, depicted in Figure 2 of the drawings is acknowledged.

The traversal is on the basis that the inventions are closely related because the claims are directed to luciferin. While it is true that the claims contain luciferin, the claims are directed to different inventions. The instantly elected invention is a product, while the nonelected subject matter is directed to methods of using and making luciferin that is not encompassed by the instant invention. In addition, the different inventions are classified in different classes. The elected invention comprising luciferin compounds are classified in various subclasses of classes 546 and 548, while the other inventions in the claims are classified in other classes such as 206 and 514.

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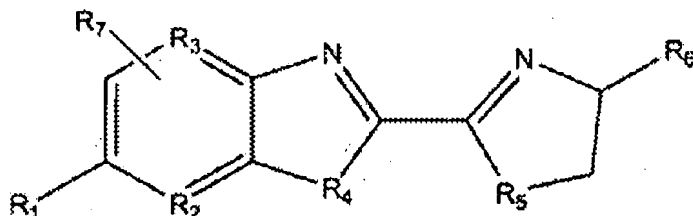
Therefore, for the above reasons, the requirement is still deemed proper and is therefore maintained.

Scope of the Elected Invention

Claims 1-167 are pending in this application.

The scope of the elected subject matter that will be examined and searched is as follows:

D-luciferin compounds of formula,



, depicted in claim 135, page 23.

Scope of Withdrawn Subject Matter

Claims 1-131 and 143-167 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 132-135, and 140 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowie, et al (Biochemistry, Vol. 12(10), 1973, pp. 1845-1852).

Applicants claims of D-luciferin derivatives relate to D-luciferin and luciferol derivatives as found in Figure 2 of the drawings. Bowie discloses compounds that anticipate the instantly claimed genus D-luciferin and luciferol derivatives on page 1846. The instant claims states that the luciferin derivatives is a substrate of a cytochrome P450 enzyme or a pro-substrate of luciferase enzyme, but a claim that merely recites a use without any active, positive steps delimiting how this use is actually practiced is not given patentable weight. In order to be given patentable weight the limitation must breathe life and meaning into the claim. In the instant case, the essence of the invention is the D-luciferin derivative, which is anticipated by the prior art of Bowie.

Claims 132-142 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,826,989, claims 1-21, columns 9-12, which teaches a process of making luciferin and luciferin derivatives.

Claims 132-142 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,035,999, claims 1-13, columns 12-14, which teaches luciferin and luciferin derivatives.

Claims 132-142 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,098,828, claims 1-5, columns 26-28, which teaches luciferin and luciferin derivatives.

Claims 132-142 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,283,180, claims 1-11, columns 10-12, which teaches luciferin and luciferin derivatives.

Claims 132-142 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,374,534, claims 1-9, columns 10-12, which teaches luciferin and luciferin derivatives.

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Claims 132-142 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,143,492, claim 5, column 67, compound XXVIII, which teaches luciferin and luciferin derivatives.

Claims 132-142 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,420,130, claim 1, column 64, compound XXVIII, which teaches luciferin and luciferin derivatives.

Claims 132-142 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,514,687, claim 3, column 81, compound XVIII, which teaches luciferin and luciferin derivatives.

Claims 132-142 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,638,713, claims 1-10, columns 60-62, which teaches luciferin and luciferin derivatives.

Obviousness Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

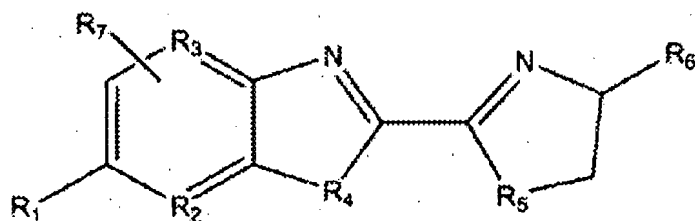
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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 132-142 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24, 68-71, and 91 of copending U.S. Pat. Appl. No. 10/444,145. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Applicants instant elected invention discloses the compounds and compositions of



formula,

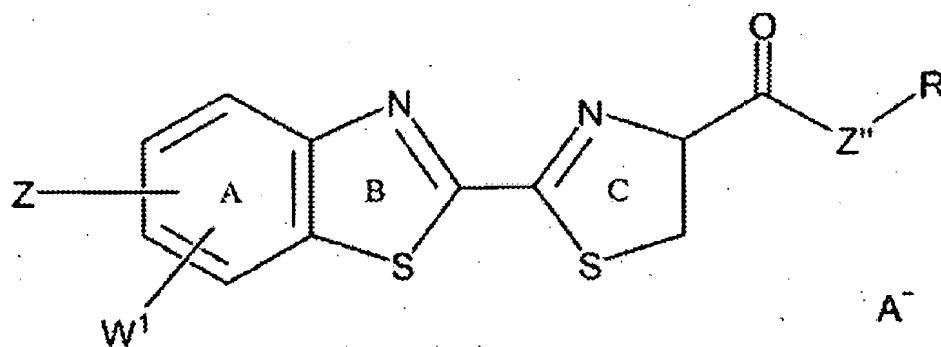
, wherein R1 is preferably an

oxygen containing functional group, R2 and R3 are carbon, R4 and R5 are sulfur, and R6 is CH₂OH or COR₁₁.

Determination of the scope and content of the co-pending application

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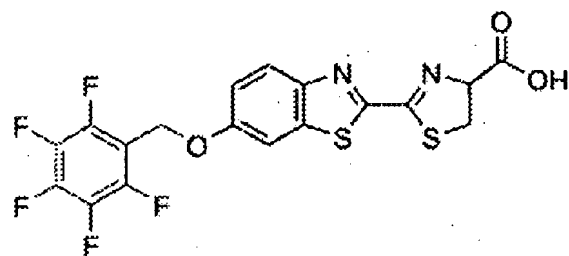
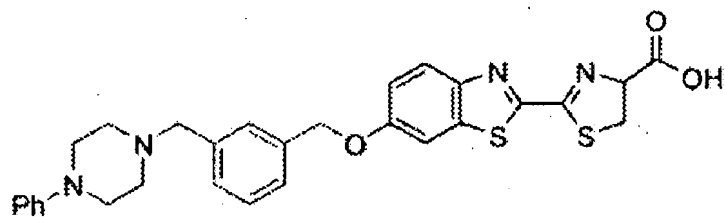
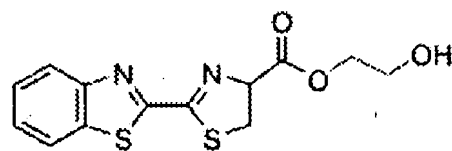
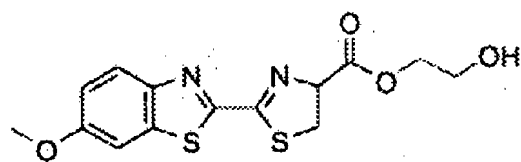
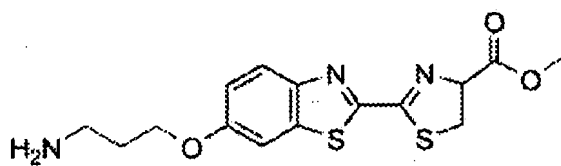
Co-pending application No. 11/444,145 claims the compound of formula (IIA),



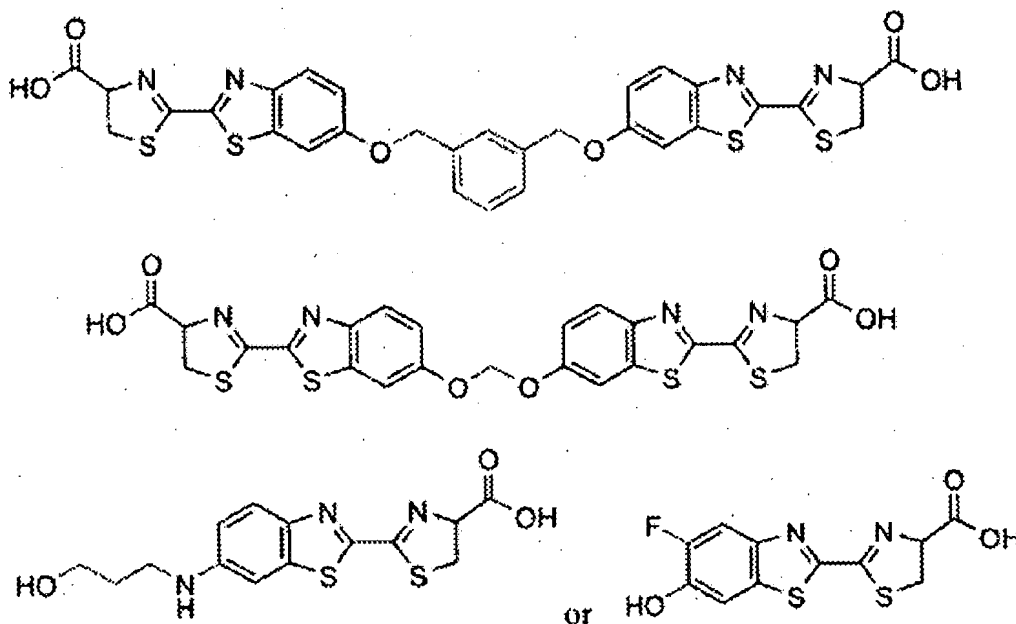
and the following

preferred species in Claim 91:

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Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between co-pending application no. 10/444,145 and the instant application is R1. In the co-pending application R1 is oxygen and nitrogen substituted moieties. In the instant application R1 can only be oxygen substituted moieties.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

One skilled in the art would have found the claimed compounds prima facie obvious over the co-pending application because the instantly claimed compounds fall within the claims of the co-pending application and the preferred species for the variables are the same, i.e. oxygen substituted moieties. Furthermore, the co-pending application teaches one of ordinary skill in the art how to create the compounds claimed in the instant application. Given the preferred embodiments and the specific embodiments listed in the claims, one of ordinary skill in the art would be motivated to produce the species common to the applications. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would

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possess similar activity. Both the instantly claimed compounds and the compounds of the co-pending applications are used as markers. Although, the conflicting claims are not identical, they are not patentably distinct from each other because applicant's instantly claimed invention is disclosed in the co-pending application. Therefore, one skilled in the art would have found the variations obvious when faced with the co-pending application because the compounds are used for the same purpose so one skilled in the art would expect similar properties and results.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 132, 133, 135, and 140 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The "derivative" of the compounds of Claim 5 is not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 132, 133, 135, and 140.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 132, 133, 135, and 140 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite for the reasons set forth above under 35 U.S.C. 112, first paragraph and the claims are drawn to the derivatives of luciferin.

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However, the "derivatives" of luciferin are not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claim is indefinite. Deletion of the term derivative would overcome the rejection.

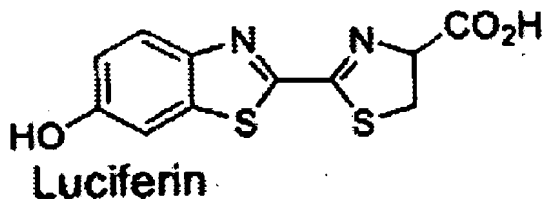
Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 135 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The definition of the terms R1, R2, R3, R4, and R5 are not supported by the specification, claims or drawings. The instantly claimed invention is D-luciferin, which is

D-luciferin and D-luciferin derivatives.



defined in Figure 2 as

or (4S)-4,5-

dihydro-2-(6-hydroxy-benzothiazolyl)-4-thiazolecarboxylic acid (See spec., page 3). D-

luciferin's core compound always contains an oxygen at the R1 position, carbon at the R2 and R3 positions, and sulfur at the R4 and R5 positions. No other atom or functional group at those

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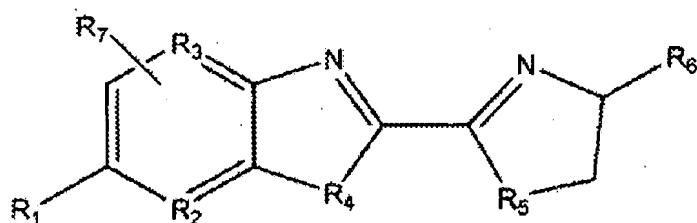
positions are supported by the instant specification, drawings, or claims. Applicant is invited to point out where in the original specification, claims or drawings the terms are supported and defined. If a proper definition cannot be found, then applicant may obviate this rejection by deleting the moieties that are not supported by the specification, claims and drawings.

Claim Rejections - 35 USC § 112, 2nd paragraph

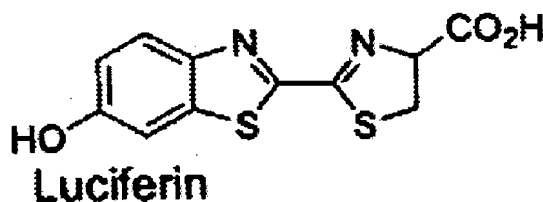
The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 135 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 135 is indefinite because the definition of "R1" is indefinite. Claim 135 is directed to a D-luciferin derivatives having the formula



, wherein R1 can be a plethora of different moieties ranging from hydrogen, hydroxy, alkoxy, cycloalkoxy, cycloalkylamino, etc... The definition of R1 is indefinite because the claim is directed to D-luciferin derivatives. D-luciferin

D-luciferin and D-luciferin derivatives.

is defined in Figure 2 as,

or (4S)-

4,5-dihydro-2-(6-hydroxy-benzothiazolyl)-4-thiazolecarboxylic acid (See spec., page 3). All of the D-luciferin derivatives in Figure 2 and the specification contain an oxygen atom at the 6' position. Therefore, the definition of R1 must contain oxygen and cannot be substituents such as hydrogen alone.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 132-142 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims contain the trademark or trade name "luciferin." Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods

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associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a class of (4S)-4,5-dihydro-2-(6-hydroxy-benzothiazolyl)-4-thiazolecarboxylic acid compounds and, accordingly, the identification/description is indefinite.

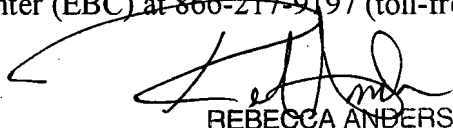
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLC



REBECCA ANDERSON
PRIMARY EXAMINER

fr Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

Date: 9 October 2007